

Textile Products Division
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CIBA-GEIGY

Contains NO CBI

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8EHQ-92-12133

88920010371

September 4, 1992



Document Processing Center (TS-790)
Office of Toxic Substances
Environmental Protection Agency
401 M. Street, SW
Washington, DC 20460

Attention: Section 8(e) Coordinator (CAP Agreement)

RE: 8E CAP - 0024

Dear Section 8(e) Coordinator:

Enclosed are the original and two copies of a study CIBA-GEIGY Corporation is submitting pursuant to the TSCA Section 8(e) Compliance Audit Program and CAP Agreement number 8E CAP-0024. We are submitting the following information, as required by the CAP Agreement:

Company Name: CIBA-GEIGY Corporation
444 Saw Mill River Road
Ardsley, New York 10502-2699

Attention: Mr. Anthony Di Battista
Manager, Regulatory Affairs & Toxic Substances
Compliance
Telephone (914) 479-2776

Tested Chemical:

Benzenesulfonic acid, 2,2'-{(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl)diimino}bis{5-methyl-, diammonium salt

also identified as: Erionyl Green GN L
Alizarine Green GNN

CAS No.: 67970-27-8

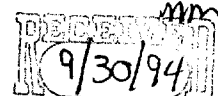
Report Title: Eye Irritation in Rabbits (Project Number: MB 79-3723 D, dated 7/13/79)

Summary: The test material was placed into the conjunctival sac of one eye of each of six rabbits. Scores for ocular irritation were recorded at 1 hour and on days 1, 2, 3, 7, 14, and 21 according to the method of Kay and Calandra. Positive corneal, iridal, and conjunctival scores were noted in all animals. On



"THE POWER OF PARTNERSHIP"

Textile Products Division



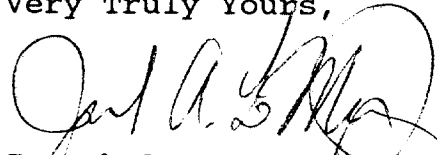
day 14, corneal scores were present in 3/6, iridal scores in 0/6 and positive conjunctival scores in 3/6 treated eyes. This study is being submitted based on potential severe eye irritation and on potential human exposure.

Category: Unit II.B.2.b

Prior Reporting: Not Applicable

Please call the undersigned at telephone number (919) 632-2889 if you have any questions about this submittal.

Very Truly Yours,



Joseph A. LoMenzo, Ph.D.
Product Stewardship Director
Textile Products Division

Enclosures

2 copies of this letter
3 copies of the study

cc: A. Di Battista

TEST FOR EYE IRRITATION IN RABBITS

FOR: TOMS RIVER CHEMICAL CORPORATION

steinsburg and wentz roads
post office box 203
spinnerstown, pennsylvania 18968
215-536-4110

Project number: MB 79-3723 D

Test started : 5/15/79
Test ended : 5/29/79

Objective : To identify ocular irritation potential

Erionyl Green GN L
44/134602/160/0

M A T E R I A L S

Sample label : Alizarine Green GNN
Concentration : 100%
Mix number : 291
TR number : 1015 00

Sample received: 5/03/79

Description : Green Powder

Severe eye irritation

A N I M A L S

Supplier(s) : Nicholas Helf
Perfection Breeders
Ace Animals

Sex : 2 Males
4 Females

New Zealand White rabbits, at least 8 weeks old when received, were equilibrated for at least one week in this laboratory. Twenty-four hours pre-test, the cornea of each animal was examined with fluorescein and cobalt blue light. Six apparently healthy rabbits, free from evidence of ocular irritation or damage, were selected for the test.

The animals were identified by cage tags noting the test material, starting date, animal number and sex.

The animals were housed 1/cage in suspended wire mesh cages (30" x 18" x 18"). Any extraneous material which might produce eye irritation was excluded from the area. Fresh Purina rabbit chow and water were freely available. The animal room, reserved exclusively for rabbits on acute tests, was maintained at 20 - 21°C and was kept clean in accordance with the standards of AAALAC of which this laboratory is an approved member.

M E T H O D S

Treatment - The test material (0.1 ml or 0.1 g) was placed once into the conjunctival sac of one eye of each of six rabbits. The lids were held together briefly to insure adequate distribution of the test material. The untreated eye of each rabbit served as a control.

Observations - The general health of the rabbits was monitored during the observation period. The ocular reactions of the cornea, iris, and conjunctiva were graded at 1 hour and at 1, 2, and 3 days after dosing. If any score was

TEST FOR EYE IRRITATION IN RABBITS

Project #: MB 79-3723 D

Page -2-

Sample # : 1015-00

noted on Day 3, the eyes were read again on Day 7. If any score was noted on Day 7, the eyes were read again on Day 14. Fluorescein and cobalt blue light were used in scoring ocular reactions on Days 1 and 3 and on Days 7 and 14, if necessary. The eyes were graded by the Draize scoring system (attached). The scores were interpreted by the method of Kay and Calandra (attached).

RESULTS

| MEAN SCORES: | <u>HOUR</u> | <u>DAYS</u> | | | | |
|--------------|-------------|-------------|----------|----------|----------|-----------|
| | <u>1</u> | <u>1</u> | <u>2</u> | <u>3</u> | <u>7</u> | <u>14</u> |
| | 25.3 | 31.7 | 34.0 | 35.2 | 21.7 | 11.3 |

CONCLUSION

The test material is severely irritating.

SUMMARY OF DATA

Positive corneal, iridal and conjunctival scores were noted in all animals.

On Day 14, corneal scores were present in 3/6, iridal scores in 0/6 and positive conjunctival scores in 3/6.

Respectfully submitted,

Oscar M. Moreno
Oscar M. Moreno, Ph.D.

Mary Teresa Moreno
Study Director

Guffey W. Miller 5/30/79 7/19/79
Quality Assurance & Dates of Inspection

Elizabeth J. Altenbach
Archivist
Submitted: 7/13/79

The raw data is filed at MB Research by project number.
The final report is filed by sponsor name and project number.

TEST FOR EYE IRRITATION IN RABBIT

Project #: MB 79-3723 D

Page -3-

Sample #: 1015-00

| An.No. | Item | Tissue | Reading | Hour | 1 | 2 | Day | 3 | 7 | 14 |
|--------|------|------------------------------------|-----------|------|----------------|----------------|----------------|----|----|----|
| | | | | 1 | | | | | | |
| 1 | A | Cornea | Opacity | a | 4 | 3 | 3 | 0 | 0 | |
| | B | | Area | 2 | 1 | 1 | 1 | 0 | 0 | |
| | | 1. Cornea Total = (AxB) x 5 | | 10 | 20 | 15 | 15 | 0 | 0 | |
| | C | Iris | | a | 1 | 1 | 1 | 1 | 0 | |
| | | 2. Iris Total = C x 5 | | | 5 | 5 | 5 | 5 | 0 | |
| | D | Conjunctiva | Redness | a | a | 2 | 3 ^c | 2 | 1 | |
| | E | | Chemosis | 3 | 3 | 3 | 3 | 2 | 1 | |
| | F | | Discharge | 3 | 3 | 3 | 2 | 1 | 0 | |
| | | 3. Conjunctiva Total = (D+E+F) x 2 | | 12 | 12 | 16 | 16 | 10 | 4 | |
| | | Totals added = 1 + 2 + 3 | | 22 | 37 | 36 | 36 | 15 | 4 | |
| | | UV Fluorescein scan | | | 3 | | 1 | 1 | 0 | |
| 2 | A | Cornea | Opacity | a | 2 | 2 | 3 | 0 | 0 | |
| | B | | Area | 3 | 1 | 1 | 1 | 0 | 0 | |
| | | 1. Cornea Total = (AxB) x 5 | | 15 | 10 | 10 | 15 | 0 | 0 | |
| | C | Iris | | a | 1 | 1 | 1 | 0 | 0 | |
| | | 2. Iris Total = C x 5 | | | 5 | 5 | 5 | 0 | 0 | |
| | D | Conjunctiva | Redness | a | 2 ^a | 2 ^a | 3 | 1 | 0 | |
| | E | | Chemosis | 3 | 3 | 3 | 2 | 1 | 0 | |
| | F | | Discharge | 3 | 3 | 3 | 2 | 1 | 0 | |
| | | 3. Conjunctiva Total = (D+E+F) x 2 | | 12 | 16 | 16 | 14 | 6 | 0 | |
| | | Totals added = 1 + 2 + 3 | | 27 | 31 | 31 | 34 | 6 | 0 | |
| | | UV fluorescein scan | | | 3 | | 1 | 0 | 0 | |
| 3 | A | Cornea | Opacity | a | 4 | 4 | 4 | 3 | 3 | |
| | B | | Area | 2 | 1 | 1 | 1 | 1 | 1 | |
| | | 1. Cornea Total = (AxB) x 5 | | 10 | 20 | 20 | 20 | 15 | 15 | |
| | C | Iris | | a | a | a | 1 | 1 | 0 | |
| | | 2. Iris Total = C x 5 | | | | | 5 | 5 | 0 | |
| | D | Conjunctiva | Redness | a | a | 3 ^a | 3 | 2 | 1 | |
| | E | | Chemosis | 3 | 3 | 3 | 2 | 2 | 2 | |
| | F | | Discharge | 3 | 3 | 3 | 2 | 1 | 1 | |
| | | 3. Conjunctiva Total = (D+E+F) x 2 | | 12 | 12 | 18 | 14 | 10 | 8 | |
| | | Totals added = 1 + 2 + 3 | | 22 | 32 | 38 | 39 | 30 | 23 | |
| | | UV fluorescein scan | | | 3 | | 1 | 1 | 1 | |

a = stained by material. c = material adhering to conjunctiva
V = vocalization post dose

TEST FOR EYE IRRITATION IN RA3BITS

Page -4-

Project #: MB 79-3723 D

Sample #: 1015-00

| An.No. | Item | Tissue | Reading | Hour 1 | 1 | 2 | Day 3 | 7 | 14 |
|--------|------|------------------------------------|-----------|-----------|----------------|----------------|----------------|----|----|
| 4 | A | Cornea | Opacity | a | 3 | 4 | 4 | 4 | 2 |
| | B | | Area | 3 | 1 | 1 | 1 | 1 | 1 |
| | | 1. Cornea Total = (AxB) x 5 | | 15 | 15 | 20 | 20 | 20 | 10 |
| | C | Iris | | a | a | a | 1 | 1 | 0 |
| | | 2. Iris Total = C x 5 | | | | | 5 | 5 | 0 |
| | D | Conjunctiva | Redness | a | a | a | 3 | 3 | 0 |
| | E | | Chemosis | 3 | 3 | 3 | 3 | 3 | 2 |
| | F | | Discharge | 3 | 3 | 3 | 2 | 3 | 1 |
| | | 3. Conjunctiva Total = (D+E+F) x 2 | | 12 | 12 | 12 | 16 | 18 | 6 |
| | | Totals added = 1 + 2 + 3 | | 27 | 27 | 32 | 41 | 43 | 16 |
| | | UV Fluorescein scan | | | 3 | | 2 | 1 | 0 |
| 5 | A | Cornea | Opacity | a | 2 | 2 | 2 | 0 | 0 |
| | B | | Area | 2 | 1 | 1 | 1 | 0 | 0 |
| | | 1. Cornea Total = (AxB) x 5 | | 10 | 10 | 10 | 10 | 0 | 0 |
| | C | Iris | | a | 1 | 1 | 0 | 0 | 0 |
| | | 2. Iris Total = C x 5 | | | 5 | 5 | 0 | 0 | 0 |
| | D | Conjunctiva | Redness | a | 2 ^a | 2 ^a | 1 | 1 | 1 |
| | E | | Chemosis | 3 | 3 | 3 | 2 | 1 | 0 |
| | F | | Discharge | 3 | 3 | 3 | 2 | 0 | 0 |
| | | 3. Conjunctiva Total = (D+E+F) x 2 | | 12 | 16 | 16 | 10 | 4 | 2 |
| | | Totals added = 1 + 2 + 3 | | 22 | 31 | 31 | 20 | 4 | 2 |
| | | UV fluorescein scan | | | 2 | | 1 | 0 | 0 |
| 6 | A | Cornea | Opacity | a | 4 | 4 | 4 | 3 | 3 |
| | B | | Area | 4 | 1 | 1 | 1 | 1 | 1 |
| | | 1. Cornea Total = (AxB) x 5 | | 20 | 20 | 20 | 20 | 15 | 15 |
| | C | Iris | | a | a | a | 1 | 1 | 0 |
| | | 2. Iris Total = C x 5 | | | | | 5 | 5 | 0 |
| | D | Conjunctiva | Redness | a | a | 2 ^a | 3 ^a | 2 | 0 |
| | E | | Chemosis | 3 | 3 | 3 | 3 | 2 | 2 |
| | F | | Discharge | 3 | 3 | 3 | 2 | 2 | 2 |
| | | 3. Conjunctiva Total = (D+E+F) x 2 | | 12 | 12 | 16 | 16 | 12 | 8 |
| | | Totals added = 1 + 2 + 3 | | 32 | 32 | 36 | 41 | 32 | 23 |
| | | UV fluorescein scan | | | 3 | | 3 | 3 | 1 |

a = stained by material

SCALE OF SCORES FOR GRADING THE SEVERITY OF OCULAR LESIONS*

| OCULAR TISSUE | DESCRIPTION | GRADING |
|---------------|---|---------|
| CORNEA | A. OPACITY - Degree of Density - Area which is most dense is read | |
| | Scattered or diffuse area, details of iris clearly visible | 1 |
| | Easily discernible translucent areas, details of iris slightly obscured | 2 |
| | Opalescent areas, no details of iris visible, size of pupil barely discernible | 3 |
| | Opaque, iris invisible | 4 |
| | B. AREA OF CORNEA INVOLVED | |
| | One quarter or less but not zero | 1 |
| | Greater than one quarter but less than one half | 2 |
| | Greater than one half but less than three quarters | 3 |
| | Greater than three quarters, up to whole area | 4 |
| | SCORE: $A \times B \times 5$ Total Maximum = 80 | |
| IRIS | A. VALUES | |
| | Folds above normal, congestion, swelling, circumcorneal injection (any or all or these or a combination of any thereof), iris still reacting to light (sluggish reaction is positive) | 1 |
| | No reaction to light, hemorrhage, gross destruction (any or all of these) | 2 |
| | SCORE: $A \times 5$ Total Maximum = 10 | |
| CONJUNCTIVA | A. REDNESS (refers to palpebral conjunctiva only excluding cornea and iris) | |
| | Vessels definitely injected above normal | 1 |
| | More diffuse, deeper crimson red, individual vessels not easily discernible | 2 |
| | Diffuse beefy red | 3 |
| | B. CHEMOSIS | |
| | Any swelling above normal (includes nictitating membrane) | 1 |
| | Obvious swelling with partial eversion of the lids | 2 |
| | Swelling with lids about half-closed | 3 |
| | Swelling with lids about half-closed to completely closed | 4 |
| | C. DISCHARGE | |
| | Any amount different from normal (does not include small amount observed in inner canthus of normal animals) | 1 |
| | Discharge with moistening of the lids and hairs just adjacent to the lids | 2 |
| | Discharge with moistening of the lids and hairs and considerable area around eye | 3 |
| | SCORE: $(A + B + C) \times 2$ Total Maximum = 20 | |

*Draize, John H. Dermal Toxicity, "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics", ASSOCIATION OF FOOD AND DRUG OFFICIALS OF THE U.S., 1959, pp 49-51

RATING OF TEST MATERIALS BASED ON EYE IRRITATION PROPERTIES*

| RATING | RANGE | DEFINITION |
|----------------------------|---------------------------|---|
| Non-irritating | 0 - 0.5 | To maintain this rating all scores at the 24 hour reading must be zero; otherwise, increase rating 1 level. |
| Practically Non-irritating | Greater than 0.5 - 2.5 | To maintain this rating, all scores at the 24 hour reading must be zero; otherwise, increase rating 1 level. |
| Minimally Irritating | Greater than 2.5 - 15.0 | To maintain this rating, all scores at the 72 hour reading must be zero; otherwise, increase rating 1 level. |
| Mildly Irritating | Greater than 15.0 - 25.0 | To maintain this rating, all scores at the 7 day reading must be zero; otherwise, increase rating 1 level. |
| Moderately Irritating | Greater than 25.0 - 50.0 | To maintain this rating, scores at 7 days must be less than or equal to 10 for 60% or more of the animals. Also, mean 7 day score must be less than or equal to 20. If 7 day mean score is less than or equal to 20 but less than 60% of the animals show scores less than 10, then no animal among those showing scores greater than 10 can exceed a score of 30 if rating is to be maintained; otherwise, increase rating 1 level. |
| Severely Irritating | Greater than 50.0 - 80.0 | To maintain this rating, scores at 7 days must be less than or equal to 30 for 60% or more of the animals. Also, mean 7 day scores must be less than or equal to 40. If 7 day mean score is less than or equal to 40 but less than 60% of the animals show scores less than or equal to 30, then no animal among those showing scores greater than 30 can exceed a score of 60 if rating is to be maintained; otherwise, increase rating 1 level. |
| Extremely Irritating | Greater than 80.0 - 110.0 | |

*Kay, J.H., Calandra, J.C., J. Soc. Cos. Chem., 13:281 - 289, 1962.

SCALE OF SCORES FOR ULTRAVIOLET FLUORESCENCE SCAN

| Reading | Grade |
|--|-------|
| Negative | 0 |
| Positive with an area one quarter or less | 1 |
| Positive with an area greater than one quarter but less than one half | 2 |
| Positive with an area greater than one half but less than three quarters | 3 |
| Positive with an area greater than three quarters, up to whole area | 4 |



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Joseph A. LoMenzo, Ph.D.
Product Stewardship Director
Textile Products Division
CIBA-GEIGY Corporation
P.O. Box 18300
Greensboro, North Carolina 27419-8300

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DEC 27 1994

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan
Terry R. O'Bryan
Risk Analysis Branch

Enclosure

12133 A



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Triage of 8(e) Submissions

Date sent to triage:

AUG 22 1985

NON-CAP

CAP

Submission number:

12133A

TSCA Inventory:

Y

N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO

AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX

SBTOX

SEN

w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX

CTOX

EPI

RTOX

GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

Other (FATE, EXPO, MET, etc.):

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1,2,4

Notes:

Contractor reviewer :

FOR

Date:

11/21/94

CECATS TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # RELQ-0992-12133 SEQ. A

TYPE: INT SUPP FLWP

SUBMITTER NAME: Ciba-Geigy Corporation

SUB. DATE: 09/04/92 OTS DATE: 09/04/92 CSRAD DATE: 09/30/94

CHEMICAL NAME: Alizarine Green GNN CAS# 67970-27-8

INFORMATION REQUESTED: FLWP DATE: 0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)
 DISPOSITION:
0639 REFER TO CHEMICAL SCREENING
0678 CAP NOTICE

0401 NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKING WITH PHS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP/USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

| INFORMATION TYPE: | P F C | INFORMATION TYPE: | P F C | INFORMATION TYPE: | P F C |
|-------------------------------|----------|--------------------------------|----------|------------------------|----------|
| 0201 ONCO (HUMAN) | 01 02 04 | 0216 EPICLIN | 01 02 04 | 0241 IMMUNO (ANIMAL) | 01 02 04 |
| 0202 ONCO (ANIMAL) | 01 02 04 | 0217 HUMAN EXPOS (PROD CONTAM) | 01 02 04 | 0242 IMMUNO (HUMAN) | 01 02 04 |
| 0203 CELL TRANS (IN VITRO) | 01 02 04 | 0218 HUMAN EXPOS (ACCIDENTAL) | 01 02 04 | 0243 CHEM/PHYS PROP | 01 02 04 |
| 0204 MUTA (IN VITRO) | 01 02 04 | 0219 HUMAN EXPOS (MONITORING) | 01 02 04 | 0244 CLASTO (IN VITRO) | 01 02 04 |
| 0205 MUTA (IN VIVO) | 01 02 04 | 0220 ECO/AQUA TOX | 01 02 04 | 0245 CLASTO (ANIMAL) | 01 02 04 |
| 0206 REPRO/TERATO (HUMAN) | 01 02 04 | 0221 ENV. OCCUR/RELEASE | 01 02 04 | 0246 CLASTO (HUMAN) | 01 02 04 |
| 0207 REPRO/TERATO (ANIMAL) | 01 02 04 | 0222 EMER INCI OF ENV CONTAM | 01 02 04 | 0247 DNA DAM/REPAIR | 01 02 04 |
| 0208 NEURO (HUMAN) | 01 02 04 | 0223 RESPONSE REQUEST DELAY | 01 02 04 | PROD/USE/PROC | 01 02 04 |
| 0209 NEURO (ANIMAL) | 01 02 04 | 0224 PROD/COMP/CHEM ID | 01 02 04 | MSDS | 01 02 04 |
| 0210 ACUTE TOX. (HUMAN) | 01 02 04 | 0225 REPORTING RATIONALE | 01 02 04 | OTHER | 01 02 04 |
| 0211 CHR. TOX. (HUMAN) | 01 02 04 | CONFIDENTIAL | 01 02 04 | | |
| 0212 ACUTE TOX. (ANIMAL) | 01 02 04 | ALLERG (HUMAN) | 01 02 04 | | |
| 0213 SUB ACUTE TOX (ANIMAL) | 01 02 04 | ALLERG (ANIMAL) | 01 02 04 | | |
| 0214 SUB CHRONIC TOX (ANIMAL) | 01 02 04 | METAB/PHARMACO (ANIMAL) | 01 02 04 | | |
| 0215 CHRONIC TOX (ANIMAL) | 01 02 04 | METAB/PHARMACO (HUMAN) | 01 02 04 | | |

USE: PRODUCTION:

TOXICOLOGICAL CONCERN:

SPECIES RBT

ONGOING REVIEW

TRIAGE DATA: NON-CBI INVENTORY

LOW
MED
HIGH

YES (DROP/REFER)
NO (CONTINUE)
REFER:

YES
NO
DETERMINE

CAS SR
NO
DETERMINE

COMMENTS:

-CPSS-

> <ID NUMBER>

8(E)-12133A

> <TOX CONCERN>

H

> <COMMENT>

EYE IRRITATION IN MALE AND FEMALE NEW ZEALAND WHITE RABBITS IS OF HIGH CONCERN. SINGLE INSTILLATIONS OF 0.1 ML OR 0.1 G INTO RIGHT-EYE CONJUNCTIVAL SACS ONLY OF 6 RABBITS WERE ASSOCIATED WITH SIGNS OF SEVERE IRRITATION THAT WAS UNABATED IN 5/6 ANIMALS UPON 14TH DAY TERMINAL OBSERVATION. SIGNS OF IRRITATION WERE MAXIMAL (MEAN DRAIZE SCORE = 35.2) AT DAY 3 OF 14-DAY OBSERVATION AND WERE CHARACTERIZED BY MODERATE TO SEVERE CONJUNCTIVITIS (6/6), MODERATE TO SEVERE FOCAL OPACITY OF THE CORNEA (6/6) AND NON-CORROSIVE IRITIS (5/6). FINAL 14TH DAY OBSERVATION FOUND UNRESOLVED SIGNS OF IRRITATION IN 5/6 ANIMALS INCLUDING PERSISTING CORNEA OPACITY (3/6).

\$\$\$\$